DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 07/01/2010 has been entered.

Notice of Amendment

1. The Amendment filed 07/01/2010 has been entered. Claims 1-5, 8-17 and 19 are pending in the application with claims 1, 12 and 15 amended, claims 6, 7 and 18 cancelled. The objection to the specification has been withdrawn. The previous 35 USC 112 rejection of claims 12 and 15 have been withdrawn in light of Applicant's amendment.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 9, 10 and 15-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claims 9 and 10 recite the limitation "the support tube" in Line 2. There is insufficient antecedent basis for this limitation in the claim.

5. Claim 15 recites “a fixing location” wherein this term has previously been defined in claim 1. It’s unclear the fixing location is meant to be a new feature or if it’s referring to the previously defined fixing location. Terms must have distinct titles from one another if they're referring to different features.

6. Claim 16 recite the limitation "the fixing device" in Line 2. There is insufficient antecedent basis for this limitation in the claim. The claim is indefinite since it’s unclear what "fixing device" applicant is referring to.

7. Claim 16 states “wherein **the fixing location is provided at the distal end of the support tube** or in the proximity thereof.” The fixing location is located on the optical system, wherein it seems implausible that the fixing location is provided at the distal end of the support tube.

8. Claim 17 recites the limitation "the surgical implement" in Line 2. There is insufficient antecedent basis for this limitation in the claim. Applicant has previously defined "a surgical instrument" and it's unclear if the surgical implement is the same as the surgical instrument.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ebling et al. (US Patent No. 5,569,161, hereinafter Ebling) in view of Osada et al. (Japanese Publication No. 05-329216, hereinafter Osada).

In regard to claim 1, Ebling discloses an endoscope comprising a flexible catheter probe **(12)** having a plurality of lumens **(Figs. 4a-4c**), an optical system **(10)** provided removably in at least one optical system lumen **(lumen through which optical fiber (14) extends)** of the catheter probe, at least one working lumen **(30, 32)** for a surgical instrument,

wherein:

the optical system which projects beyond the proximal end of the catheter probe is guided movably in a flexible tube **(60)**; which is elastically resilient in a longitudinal direction thereof to prestress the optical system toward the distal end of the probe **(Col. 8, Lines 3-10)** and its proximal end is fixedly connected at a fixing location to the optical system projecting beyond the proximal end of the catheter probe **(Fig. 11 shows the proximal end of the flexible tube connected to the optical system)** and its distal end

is releasably connected to the proximal end of the optical system lumen of the catheter probe **(Fig. 11, male and female bayonet connectors (20, 22))**;

the distal end of the optical system is pressed by the tube against a translucent cover which closes the distal end of the optical system lumen **(Col. 8, Lines 3-10)**; and

the catheter probe is a disposable component **(the catheter probe is capable of being disposed of after surgery is performed)**.

Ebling does not expressly teach of the catheter probe comprising a handle provided at the proximal end of the probe and a control element which is fixed to the distal end of the probe or in the proximity thereof for bending the end of the probe and is guided movably in the axial direction at the probe, a rotary bearing provided on the handle; at its proximal end the catheter probe is non-rotatably connected by a releasable fixing device to a manually actuatable rotary portion which is mounted rotatably to the handle in the rotary bearing through which the control element is displaceably guided; the proximal end of the control element is releasably connected to a slider mounted to the handle.

Osada teaches of a catheter tube having a plurality of lumens, where a proximal connector (15) to one of the plurality of lumens is provided with a tension implement (16). The tension implement (16) is comprised of a cylinder body (161, rotary portion) fixedly connected to the proximal connector (15) having a plurality of threads (162) formed therein. The tension implement (16) further comprises a plunger (163, slider) having a flange portion (166, handle) at its proximal end and a threaded section (165, rotary bearing) at its distal end. A wire (8) is fixed at the distal end of the catheter tube

and is attached to the proximal end of the plunger by a stop (168), thereby when the flange portion of the plunger is rotated the threaded sections (165,162) cause the wire (8) to advance distally or proximally, thereby articulating the distal end of the catheter tube (Figs. 5-6).

Ebling teaches the endoscope can be formed to have articulation and steering means formed within the sleeve. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to provide the apparatus of Ebling with the Steering Mechanism of Osada providing the physician with a means of steering the distal end of the catheter to vary the angle of view of the camera as well as to navigate the catheter within the body.

11. Claims 1-5, 8-11, 14, 16, 17 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ebling et al. (US Patent No. 5,569,161, hereinafter Ebling) in view of Gould et al. (US Patent No. 4,586,923, hereinafter Gould).

In regard to claim 1, Ebling discloses an endoscope comprising a flexible catheter probe **(12)** having a plurality of lumens **(Figs. 4a-4c**), an optical system **(10)** provided removably in at least one optical system lumen **(lumen through which optical fiber (14) extends)** of the catheter probe, at least one working lumen **(30, 32)** for a surgical instrument,

wherein:

the optical system which projects beyond the proximal end of the catheter probe is guided movably in a flexible tube **(60)**; which is elastically resilient in a longitudinal direction thereof to prestress the optical system toward the distal end of the probe **(Col. 8, Lines 3-10)** and its proximal end is fixedly connected at a fixing location to the optical system projecting beyond the proximal end of the catheter probe **(Fig. 11 shows the proximal end of the flexible tube connected to the optical system)** and its distal end is releasably connected to the proximal end of the optical system lumen of the catheter probe **(Fig. 11, male and female bayonet connectors (20, 22))**;

the distal end of the optical system is pressed by the tube against a translucent cover which closes the distal end of the optical system lumen **(Col. 8, Lines 3-10)**; and

the catheter probe is a disposable component **(the catheter probe is capable of being disposed of after surgery is performed)**.

Ebling does not expressly teach of the catheter probe comprising a handle provided at the proximal end of the probe and a control element which is fixed to the distal end of the probe or in the proximity thereof for bending the end of the probe and is guided movably in the axial direction at the probe, a rotary bearing provided on the handle; at its proximal end the catheter probe is non-rotatably connected by a releasable fixing device to a manually actuatable rotary portion which is mounted rotatably to the handle in the rotary bearing through which the control element is displaceably guided; the proximal end of the control element is releasably connected to a slider mounted to the handle.

Gould teaches of a multi-lumen catheter having various mechanism for manipulating a pull wire for bending the distal end of the catheter. Primarily, Fig. 7 teaches of a catheter with a housing (40) comprising a second arm member (48) having a threaded section (133) at a proximal end thereof that mate with internal threads (134) formed on a cap member (138). The cap member includes a ball bearing assembly (140) which includes an inner race (142), outer race (144) and ball bearings (146) therebetween. The ball bearing assembly is slidably received into a shoulder (150) which is journaled into the proximal end of the second arm of the housing (40) and is movable with the cap member relative to the proximal end of the second arm when the cap member is rotated about and relative to the proximal end of the second arm. The proximal end of the pull wire (60) is connected to a washer (152) which is freely mounted between a surface of the cap member and the inner race (142) of the ball bearing assembly. When the cap member is rotated in a clockwise direction, the ball bearing assembly moves rearwardly together with the cap member relative to the trident housing so that the washer also moves rearwardly, thereby pulling the wire and causing the tip of the catheter to bend. Since the washer is mounted freely between the surface of the cap member and the inner race of the ball bearing assembly, the washer is non-rotatable relative to the cap member when the cap member is rotated so that the pull wire is not twisted by the rotating action of the cap member.

Ebling teaches the endoscope can be formed to have articulation and steering means formed within the sleeve. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to provide the apparatus of Ebling

with the Steering Mechanism of Gould providing the physician with a means of steering the distal end of the catheter to vary the angle of view of the camera as well as to navigate the catheter within the body.

In regard to claim 2, Ebling teaches wherein the fixing location is provided at the proximal end of the tube **(Fig. 11 shows the flexible tube (60) attached to a tubular member of the optical system at its proximal end)**.

In regard to claim 3, Ebling teaches wherein provided at the proximal end of the optical system is a connecting portion which is connectable to an illumination device and/or to an ocular **(16. 18)**.

In regard to claim 4, Ebling teaches wherein the fixing location is provided at the connecting portion **(Fig. 11 shows the eyepiece (16) provided at the fixing location / connecting portion)**.

In regard to claim 5, Ebling teaches wherein the flexible tube is arranged outside the handle **(Fig. 6 shows the flexible tube being separate of the handle)**.

In regard to claim 8, Gould teaches wherein the rotary bearing has a manually actuable rotary portion which is non- rotatably connected to the catheter probe **(the cap**

member (138) rotates with the rotary bearing, wherein the probe is prevented from rotating).

In regard to claim 9, Gould teaches wherein the control element is passed through the fixing device **(the control wire pass through the threaded sections (133, 134) being regarded as the fixing device)**.

In regard to claim 10, Gould teaches wherein the proximal end of the control element is passed through the fixing device **(the control wire pass through the threaded sections (133, 134) being regarded as the fixing device)**.

In regard to claim 11, Ebling teaches wherein the catheter has a balloon **(54)** to which a dilation medium can be fed by way of a balloon lumen in the catheter probe **(Col. 9, Lines 8-9)**.

In regard to claim 14, Gould teaches wherein the control element is fixed to the distal end of the probe by a shrink tube or by an adhesive **(Col. 7, Lines 7-12)**.

In regard to claim 16, Gould teaches wherein the fixing location **(34)** is provided at the distal end of the support tube **(23)** or in proximity thereof.

In regard to claim 17, Ebling teaches wherein the surgical implement is removable from the at least one working lumen or is incorporated or integrated into the catheter probe **(a surgical implement, i.e. a guidewire, forceps, illumination device, can be removable or integrated within the catheter probe)**.

In regard to claim 19, Ebling teaches wherein the catheter probe is an injection molded component or an extruded component **(The probe is capable of being formed from a molding or extruding process, furthermore, Ebling teaches of the body (28) being formed from a molding process, Col. 5, Lines 66-67)**.

12. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ebling et al. (US Patent No. 5,569,161, hereinafter Ebling) in view of Gould et al. (US Patent No. 4,586,923, hereinafter Gould), as applied to claim 11, and further in view of Kuntz et al. (US Patent No. 4,909,258, hereinafter Kuntz

In regard to claim 12, Ebling as modified by Gould do not expressly teach wherein a guide wire can be guided through a guide wire lumen which extends from the distal end of the probe to an exit opening in the catheter, the exit opening being behind the balloon.

Kuntz teaches of a multi-lumen catheter (22) with a balloon (30) formed on the distal end of the catheter. The catheter contains a guidewire exit port (32) proximal to

the balloon allowing a guide to be inserted into a lumen that's orthogonal to the longitudinal axis of the catheter body (Fig. 6).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to provide the apparatus of Ebling and Gould with the guidewire lumen (32) of Kuntz thereby allowing the physician to insert the guidewire into body lumens that are arranged orthogonally to the longitudinal axis of the catheter, wherein if necessary the balloon can be inflated to occlude an adjacent body lumen or inflated to stabilize the catheter allowing insertion of the guidewire.

13. Claim 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ebling et al. (US Patent No. 5,569,161, hereinafter Ebling) in view of Gould et al. (US Patent No. 4,586,923, hereinafter Gould), as applied to claim 9, and further in view of Shockey (U.S. Patent 5,168,864).

In regard to claim 13, Ebling as modified by Gould do not disclose that the control element is arranged in a flexible support tube which is arranged in a control lumen of the catheter probe and terminates at a given spacing from the distal end of the probe, wherein the given spacing corresponds approximately to the length of a distal portion of the probe, which is to be bent over by the control element.

Shockey discloses a deflectable probe (10, Fig. 1) in which the deflecting motion is actuated by a control element (24) supported by a flexible support tube (20). The tube is arranged in a control lumen (22) of the probe and terminates at a given spacing from

the distal end of the probe, wherein the given space (D1, Figs. 2-3) corresponds approximately to the length of a distal portion o f the probe which is bent over by the control element (Col. 4, lines 34-42). The length of the support member inserted into the probe is adjustable by valve (21, Fig. 1) and therefore the support member allows the “physician to selectively adjust and adapt the radius R of the flexible tip portion" (Col. 4, lines 59-62).

It therefore would have been obvious to one of ordinary skill in the art at the time of the invention to modify Gould’s steering mechanism to consist of the adjustable support member and valve as disclosed by Shockey in order to have the advantages taught by Shockey, as noted above.

In regard to claim 14, Shockey discloses an analogous device in which a control element is fixed to the distal end of a probe by an adhesive (Col. 4, lines 7-8). One of ordinary skill in the art would appreciate that in order for the proper functioning of the invention, the control element would need to be fixed to the distal end of the probe and that the method of fixing does not matter.

It therefore would have been obvious to one of ordinary skill in the art at the time of the invention to provide a suitable means of fixation as disclosed by Shockey to fixedly secure the control element and still predictably arrive at the same working invention.

In regard to claim 15, Shockey discloses that a support tube is fixed at a fixing location in the axial direction (wherein the tube is fixed at point 21, Fig. 1, when the clamp is closed). The remaining portion of the support tube is considered to be movable with respect to the inside wall of the control lumen because the support tube is not fixedly attached to the control lumen.

In regard to claim 16, Shockey discloses, in another embodiment, that there are two tubes that offer support to the control element. Tube 64 is axially movable, controlled by clamp 68, and tube 60, which is fixedly received within the lumen 63 (Col. 5, lines 13-16). In order to be fixedly received, the tube has to be fixed at some fixing location. Although Shockey is silent as to the exact fixing location of the first tube, one of ordinary skill in the art would appreciate that in order for the proper functioning of the invention, the tube would just need to be fixed at a location and the exact location of the fixing does not matter. Therefore, it would have been obvious to one of ordinary skill in the art to fix the tube at the distal end of the support tube and still arrive at the same predictable endoscope.

Response to Arguments

14. Applicant's arguments with respect to claims 1-5, 8-17 and 19 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RYAN HENDERSON whose telephone number is (571)270-1430. The examiner can normally be reached on M-F 7:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Matt Kasztejna can be reached on (571)272-6086. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. H./
Examiner, Art Unit 3779
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